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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/732,983

12/10/2003

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S63.2B-10888-US01

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490 7590 08/20/2008  
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EXAMINER

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ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 05/15/2008 in which claims 1, 3, and 23 were amended. Currently claims 1-12, 14, and 16-29 are pending for examination with claims 8-9, 11-12 and 28 withdrawn from a previous election restriction. Examiner also acknowledges the amendments to the disclosure substituting the specification paragraph and changing the title of the application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) that was submitted on 08/06/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

### ***Claim Objections***

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 appears to incorporate the same limitation as claim 2, which is also dependant on base claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Regarding claim 23, the statement "...the shaft and wherein the second tubular layer and the shaft are incompatible for thermal bonding directly to one another such that there is substantial covalent bonding between the second tubular layer and the shaft after being thermally bonded directly to one another..." seems contrary to Applicant's invention and amended specification. The second layer and the catheter shaft are unable to be directly thermally bonded and are bonded indirectly to each other using a "tie layer" which is thermally compatible with both layers. Therefore Examiner does not understand how the claimed direct thermal bonding the second layer and shaft can be covalent bonding between them. For the purposes of examination the Examiner will assume that they are indirectly thermally bonded through the tie layer as disclosed in Applicant's specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 18, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwab et al. (USPN5,769,819). Schwab et al. discloses a catheter distal tip component.

Regarding claims 1, 3-4, 18 and 29, Schwab et al. discloses a catheter (5, Figure 1) comprising, a proximal portion, a distal portion, the distal portion terminating at a distal end (near 60), a shaft (65, 55), the shaft having a proximal portion, a distal

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portion, the distal portion terminating at a distal end, and a conduit (through line 60) there through, and a distal tip layer (20), the distal tip layer being in the form of a tube and being positioned about the distal portion of the shaft, the distal tip layer having a proximal end and a distal end, wherein the distal end of the distal tip layer extends distally to at least the distal end of the shaft and forms at least a portion of the distal end of the catheter and is formed of a different material (adhesive) the catheter further comprising a medical balloon (35), the balloon (35) having a body portion position between a proximal waist and a distal waist, wherein the distal waist (40, 45) is connected to the distal portion of the shaft and is positioned at least adjacent to the proximal end of the distal tip layer and wherein the distal tip layer is circumferentially between the distal waist and the shaft, such that the distal waist is not in contact with the shaft (col 5, ln 10-30), and wherein the shaft (section denoted by 30) extends distally beyond the distal waist, the distal end of the shaft having a first longitudinal portion (near 70) having a first diameter, wherein in the first longitudinal portion is radially (near 70) at least partially within the body portion of the balloon, and a second longitudinal portion (near 40) having a second diameter, the second longitudinal portion being immediately adjacent to the first longitudinal portion, wherein the first diameter is greater than the second diameter (see stepped portion between elements 70 and 30), the second longitudinal portion forming a circumferentially stepped down portion from the first longitudinal portion, wherein the distal tip layer (20) is positioned around and conforms to the circumferentially stepped down portion (tapered section near 45, Figures 1-3).

***Claim Rejections - 35 USC § 102***

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (USPN6,010,521). Lee et al. discloses a catheter member with a bondable layer.

Regarding claims 23-25, Lee et al. discloses a catheter (12, Figure 1) comprising, a shaft (22), a first tubular layer (24) circumferentially about the shaft and a second tubular (15) layer circumferentially about the shaft, the shaft (22) and the first (24) and second (15) tubular layers being thermal bonded together (col 2, col 4, In 25-65), the first tubular layer having an inner side and an outer side and being at least partially circumferentially between the second tubular layer and the shaft, wherein the outer side of the first tubular layer is thermally bonded directly to the second tubular layer and the inner side of the first tubular layer is thermally bonded directly to the shaft and wherein the second tubular layer and the shaft are incompatible for thermal bonding directly to one another such that there is substantial covalent bonding between the second tubular layer and the shaft after being thermally bonded directly to one another (Figure 1, cols 1-2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 16 are rejected under 35 U.S.C 103(a) as being unpatentable over Schwab et al. (USPN5,769,819) in view of Wijay et al. (USPN4,921,483). Schwab et al. meets the claim limitations as described above except for the distal layer extending beyond the shaft.

However, Wijay et al. teaches an angioplasty catheter.

Regarding claims 2 and 16, Wijay et al. teaches Wijay et al. discloses a catheter comprising: a proximal portion, a distal portion, the distal portion terminating at a distal end, a shaft (20) with a stepped down portion (26), the shaft having a proximal portion, a distal portion, the distal portion terminating at a distal end, and a conduit there through (lumen of 26), and a distal tip layer (72), the distal tip layer (72) being in the form of a tube (Figures 3 and 5) and being positioned about the distal portion of the shaft, the distal tip layer having a proximal end and a distal end, wherein the distal end of the distal tip layer (72) extends distally to at least the distal end of the shaft (26) (from about 32-74) and forms at least a portion of the distal end of the catheter, the catheter further comprising a medical balloon (28), the balloon having a body portion positioned between a proximal waist and a distal waist, wherein the distal waist is connected to the

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distal portion of the shaft and is positioned at least adjacent to the proximal end of the distal tip layer which is stepped to receive the distal waist, and wherein the distal tip layer is circumferentially between the distal and the shaft (Figure 3), such that the distal waist is not in contact with the shaft and wherein the shaft (26) extends distally beyond the distal waist (of 28) with the distal tip (72) extending distally beyond the shaft (26) (cols 1-2) at a fixed distance (col 7, ln 40-70).

At the time of the invention, it would have been obvious to incorporate the increased length of the distal tip layer of the Wijay et al. to the system of Schwab et al. in order to add a soft distal end for decreased vascular trauma during insertion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Wijay et al. (cols 1-2).

### ***Claim Rejections - 35 USC § 103***

Claims 6-7 are rejected under 35 U.S.C 103(a) as being unpatentable over Schwab et al. (USPN5,769,819) in view of Larson et al. (6,048,338). Schwab et al. meets the claim limitations as described above except for a spiral cut layer.

However, Larson et al. teaches a catheter with a spiral cut transition member with multiple layers.

Regarding claims 6-7, Larson et al. teaches catheter (200) with a multi-layer construction comprising a spiral cut member (126) (Figure 5).

At the time of the invention, it would have been obvious to add the spiral cut member of Larson et al. to the system of Duchamp in order to improve catheter



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flexibility and catheter tracking (col 2, ln 1-25). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Larson et al. (see abstract).

***Claim Rejections - 35 USC § 103***

Claims 5, 10, 17 and 26-27 are rejected under 35 U.S.C 103(a) as being unpatentable over Schwab et al. (or Lee et al.). Schwab et al. (or Lee et al.) meets the claim limitations as described above except for the specific disclosed materials and tip length.

Regarding claims 5 and 26-27, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Schwab et al. (or Lee et al.) with the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claims 10 and 17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Schwab et al. with the tip length claimed by Applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Claim Rejections - 35 USC § 103***

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwab et al. (USPN5,769,819) in view of Lee et al. (USPN6,010,521). Schwab et al. meets the claim limitations as described above except for the thermally bonded intermediate layer.

However, Lee et al. teaches a catheter member with a bondable layer.

Regarding claims 19-22, Lee et al. teaches Lee et al. discloses a catheter (12, Figure 1) comprising, a shaft (22), a first tubular layer (24) circumferentially about the shaft and a second tubular (15) layer circumferentially about the shaft, the shaft (22) and the first (24) and second (15) tubular layers being thermal bonded together (col 2, col 4, ln 25-65), the first tubular layer having an inner side and an outer side and being at least partially circumferentially between the second tubular layer and the shaft, wherein the outer side of the first tubular layer is thermally bonded directly to the second tubular layer and the inner side of the first tubular layer is thermally bonded directly to the shaft and wherein the second tubular layer and the shaft are incompatible for thermal bonding directly to one another such that there is substantial covalent bonding between the second tubular layer and the shaft after being thermally bonded directly to one another (Figure 1, cols 1-2).

At the time of the invention, it would have been obvious to replace the adhesive bonded layer of Schwab et al. with the thermally bonded layer of Lee et al. in order to add increased strength to the bond. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the

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art would have combined the teachings in the references in light of the disclosure of Lee et al. (cols 1-2).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7, 10, 16-27 and 29 have been considered but are moot in view of the new ground(s) of rejection.

### ***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition and further clarification of the spatial location/structure and length of the spiral cut layer to the independent claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/17/2008

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Examiner, Art Unit 3763

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